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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,683	11/04/2003	Robert C. Brunham	1038-1273 MIS:ah	2991

7590 05/09/2005

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,683	BRUNHAM	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-22 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22,24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 19-22 and 24-28 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

1. The information disclosure statement filed October 28, 2004 has been considered.

Rejections Maintained

1. Claims 19, 22, 25, 27-28 rejected under 35 U.S.C. 102(e) as being anticipated by Gurtiss III (US Pat. 5,389,368), is maintained for reasons of record in paper number 10152004, and responses set forth below.

2. Claims 20-21, 24, and 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Gurtiss, III (US Pat. 5,389,368) as applied to claims 19, 22, 25, 27-28 above, in view of Burnham (WO98/02546), is maintained for reasons of record in paper number 10152004, and responses set forth below.

Response to Arguments

2. Applicant's arguments filed January 21, 2005 have been fully considered but they are not persuasive.

3. The rejection of claims 19, 22, 25, 27-28 under 35 U.S.C. 102(e) as being anticipated by Gurtiss III (US Pat. 5,389,368) is traversed on the grounds that host cell of claim 19 comprises a plasmid DNA which is "released into the cytoplasm of the infected host cells and the encoded gene expressed in the host cells (Remarks/Arguments page 3, paragraph 3)."

4. It is the position of the examiner that Gurtiss III (US Pat. 5,389,368) disclose Salmonella typhimurium, S. typhi and other Salmonella species to evidence the ability to attach to, invade and proliferate in the cells of the gut-associated lymphoid tissue (GALT; Peyer's Patches) (Carter and Collins, J. Exp. Med. 139: 1189-1203, (1974)) (see US Pat. 5,389,368: col. 1, lines 66-68 and col. 2, lines 1-18), thus the Chlamydia protein (Gurtiss III, claim 6) is expressed in the eukaryotic host cell, as Salmonella is an intracellular pathogen. Inherently the reference anticipates the instantly claimed invention because Salmonella-mediated delivery of a nucleic acid molecule encoding a Chlamydia antigen to the GALT elicits an immune response because the avirulent Salmonella mutants have lost the ability to cause disease without impairment in their ability to attach to and invade the GALT , and the instantly claimed invention has not been distinguished from the invention of Gurtiss III, US Pat. 5,389,368.

With respect Applicant's statement that the allowed application, now US Pat. 6,676,949, was issued over the US Pat. 5,389,368 Patent and the instantly pending claims also define over the applied reference, it is the position of the examiner that the allowed claims are directed to method claims; a new use for a known composition. The rejection of the instantly claimed composition claims 19, 22, 25, 27-28 is maintained for reason of record.

5. Applicant's representative asserts that "it is the promoter in the DNA construct that directs the expression of the MOMP in the host cells only and not in the attenuated bacteria."

> It is the position of the examiner that Applicant's arguments are not commensurate in scope with what is now claimed in claims 19, 22, 25, 27 and 28, the claims against which Gurtiss, III was applied. While claim 20 recites the species of Chlamydial antigen MOMP, Gurtiss III was not applied under 35 USC 102 against claim 20, and the Salmonella strains are considered to be carrier strains of attenuated bacteria for the

expression of a heterologous immunogen in a host cell, specifically the cells of the host GALT.

6. The rejection of claims 20-21, 24, and 26 under 35 U.S.C. 103(a) as being unpatentable over Gurtiss, III (US Pat. 5,389,368) as applied to claims 19, 22, 25, 27-28 above, in view of Brunham (WO98/02546) is traversed on the grounds that "the Examiner does not refer to any teaching of Brunham which would remedy the basic defects of Gurtiss as discussed above.

7. It is the position of the examiner that Burnham describes additional means for the expression of a Chlamydial antigen in a host cell, wherein Gurtiss III described an attenuated Salmonella typhimurium bacteria harboring an expression vector that comprised a nucleic acid molecule encoding a Chlamydial antigen, wherein the attenuated carrier Salmonella strain expressed the nucleic acid gene product (see Gurtiss III, col. 6, line 18; col. 8, lines 49-51 and col. 9, lines 47-48) intracellularlly for induction of an immune response and Burnham described a species of Chlamydial antigen coding sequence, specifically the nucleic acid that encodes a MOMP protein from trachomatis under the control of a cytomegalovirus promoter placed in the plasmid vector is pcDNA3.

8. Brunham was applied in combination with Gurtiss III because the two references are analogous art in teaching nucleic acid molecules that encode Chlamydia antigens in vectors, and Burnham teaches a species of protective Chlamydial MOMP or MOMP fragment antigen thereof obtained from Chlamydia trachomatis, and incorporated the nucleic acid into a plasmid that comprised a cytomegalovirus promoter for expression of MOMP therefrom, (see Burnham, page 25, Table 2; and claims 4, 6, 16). No unexpected results have been made of record to obviate

the rejection of Gurtiss III in view of Brunham. The rejection is maintained for reasons of record and responses set forth above.

Newly Issued Patent (March 29, 2005) to a Common Inventor (Murdin)/New Grounds of Rejection

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,5,8,10, 15, and 17 of U.S. Patent No. 6,872,814. Although the conflicting claims are not identical, they are not patentably distinct from each other because in light of the definition of the term promoter in US Patent No. 6,872,814 to include promoters that will express a heterologous nucleic acid in a human cell (see '814, col. 13, lines 54-60 and col. 14, lines 1-3 and 38-40, cytomegalovirus promoter), the allowed species of attenuated bacterial vaccine vector, specifically Bacille bilie de Calmette-Guerin, an art recognized attenuated strain of bacteria, that comprises a Chlamydial nucleic acid operatively linked to a promoter for the expression of the encoded Chlamydial antigen in the host cell, anticipates the instantly claimed genus of attenuated strains of bacterium of instant claim 19.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
May 2, 2005

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SUPERVISORY PATENT EXAMINER
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